

U.S. Navy Human Research Protection Program News

9 December 2004

Update on Re-Alignment of the Navy's HRPP; Management Plan; Assurances

The Office of Research Integrity and Ethics (ORIE) was disestablished in October 2004. The Human Research Protection Program (HRPP), formerly under ORIE, is currently in transition. The Surgeon General (SG) of the Navy and the Chief of Naval Research (CNR) have chartered a working group to identify the most efficient, cost-effective management model for the Navy's Human Research Protection Program. One of the objectives of the working group is to address the Director of Defense Research and Engineering's (DDR&E) concern that there are two points of accountability in U.S. Navy policy for human subjects protection in the Navy. The SG is responsible for oversight of the human research protection program within intramural Navy and Marine Corps activities, including all research involving active duty, SECNAV designees and beneficiaries. The responsibility for oversight of extramural human research not involving these populations resides with the CNR. DDR&E indicated in their 22 October 2004 Action Memo that "splitting implementation of DoDD 3216.2 across RDA organizations (ASN(RDA) and Chief of Naval Research) and an organization of the Chief of Naval Operations (Bureau of Medicine and Surgery) unnecessarily risks establishment of multiple Navy ethical standards and implementing processes." In addition to addressing this issue, the Navy, as well as the other Services and DoD agencies, must submit to DDR&E a "Management Plan" describing how we will implement DoDD 3216.2. DDR&E will cancel all DoD assurances for conducting human subject research as of 31 December 2004 pending receipt and approval of a Management Plan. The Navy SG submitted a request to DDR&E in mid-November for an extension to 30 April 2005 for submission of the Management Plan. We are still awaiting a response from DDR&E, but we have no reason to expect that an extension will not be granted.

New HRPP Policy

Once we determine where the Navy's HRPP will reside organizationally, a working group will draft the new policy for Human Research Protections. This will be sent for comment to the Navy R&D labs, MTFs and System Commands.

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Current HRPP Staff and Contact Information

Director 301.530.5734

Deputy Director 301.530.6145

Clinical Investigations Program 301.530.3497

HRPP Fax Number 301.564.9285

HRPP Mailing Address

Human Research Protection Program
Bureau of Medicine and Surgery
Department of Navy
6700A Rockledge Drive, Suite 200
Bethesda, MD 20892

HRPP Directory

Please see the attached Excel file for the Navy HRPP Directory. If you find any errors or omissions, please contact the Human Research Protection Program office.